Overview of Bensulide
Risk Assessment

June 15, 1999

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the organophosphate pesticide Bensulide, as presented fully in the documents, "Human Health Risk Assessment -- Bensulide," dated June 15, 1999, and "Environmental Risk Assessment -- Bensulide," dated June 14, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments. This summary was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

These risk assessments for bensulide will be placed in the Pesticide Docket on June 16, 1999, and a 60-day comment period on risk management will begin.

It has been determined that the organophosphates (OPs) share a common mechanism of toxicity, the inhibition of cholinesterase levels. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water and non-occupational exposure resulting from all uses of OPs. Currently, the Agency is developing the draft methodology needed to conduct such an assessment with guidance/advice provided by the Science Advisory Panel. It is anticipated that this draft methodology will be available for comment and scientific review in the late summer/early fall of 1999. Consequently, the risks summarized in this document are only for bensulide.

Use Profile

- **Herbicide** registered for pre-emergent, pre-plant control of annual weeds and grasses for use on vegetable crops (lettuce, onions, melons, other minor crops) and non-food (turf and ornamentals, residential lawns) uses.

- **Registrations**: EC (emulsifiable concentrate) formulations, for both agricultural and turf use; granular formulations for homeowner and professional use on turf**.**

- **Methods of Application**: Broadcast; chemigation; soil band treatment; groundboom; spray.

- **Use Rates**: Agricultural use rate ranges depending on crop from 3 to 6 lbs/ai/acre, applied once a year; turf use rate is 7.5 to 12.5 lbs ai/acre, applied up to twice a year on established turf.

- **Annual Poundage:** 550,000 (active ingredient)

- **Registrant**: Gowan Company

Human Health Risk Assessment

Revisions to the Preliminary Human Health Risk Assessment include:

- Use of a 21-day dermal toxicity study to determine dermal exposure (i.e., default dermal absorption factor not applied) in the assessment of occupational and residential risks.

- Use of data from a turf transferable residue study in the assessment of post-application occupational and residential risks.

- Use of separate toxicological endpoints for dermal and inhalation exposures.

- Exposure scenarios were added to occupational handler risk assessment based on registrant comments on bensulide use on golf courses.

- Considered exposure to children from non-dietary ingestion of bensulide-treated turf.

Acute Dietary (Food) Risk

Acute dietary risk is calculated considering what is eaten in one day (in this instance, the individual who consumed the most) and maximum, or high-end residue values in the food. A risk estimate that is less than 100% of the acute Reference Dose (aRfD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's risk concerns.

The bensulide acute dietary risk from food is well below the Agency's level of concern (i.e., less

than 100% acute RfD is utilized).

- End point is plasma cholinesterase inhibition from an acute neurotoxicity study in rats (NOAEL= 15 mg/kgBW/day)

- Uncertainty Factor (UF) is 100 (the standard uncertainty factor) to account for both interspecies extrapolation and intraspecies variability. The 10X FQPA safety factor was removed based on studies that indicated no increased sensitivity to infants and children.

  The acute RfD is calculated to be 0.15 mg/kg/day.

- The risk assessment was conducted assuming 100% of the registered commodities were treated, used monitoring data (no detects found), tolerance level residues, and USDA consumption data for 1989-91. It was a refined, Tier I assessment.

- For the most exposed subgroups, children (1-6 years) and infants (<1 year), the % acute RfD values are less than 1% at the 95th percentile of exposure.

- Further refinements can be made with the use of a probabilistic (Monte Carlo) analysis.

Chronic Dietary (Food) Risk

Chronic dietary risk is calculated by using the average consumption value for food and average residue values on those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic RfD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's risk concern.

The bensulide chronic dietary risk from food only is well below the Agency's level of concern (i.e., less than 100% of the chronic RfD is utilized).

- End point is cholinesterase inhibition in plasma (both sexes) and brain (males) from a dog feeding study (NOAEL= 0.5mg/kg)

- Uncertainty Factor is 100 (the standard uncertainty factor) to account for both interspecies extrapolation and intraspecies variability. As in the acute dietary assessment, the 10X FQPA safety factor was removed.

- The chronic RfD is calculated to be 0.005 mg/kg/day.

- The risk assessment was conducted using tolerance levels (based on non-detectable residues), percent crop treated values, and USDA consumption data for 1989-91.

- For the most exposed subgroups, children (1-6 years), and infants (< 1 year), the % chronic RfD values are less than 1%.

- Refinements can be made using monitoring data; however, given the low chronic dietary risk estimate based on tolerance level residues and incorporating percent crop treated information, the Agency determined that calculation of chronic anticipated residues from monitoring data is not warranted at this time.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate. To determine the maximum allowable contribution of treated water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food, then determines a "drinking water level of comparison."

The acute drinking water risks calculated for ground and surface water, and the chronic drinking water risk calculated for groundwater for bensulide do not exceed the Agency's level of concern. The chronic drinking water risk calculated for surface water indicates a potential to exceed the Agency's level of concern.

- Preliminary risk assessment for bensulide did not establish Drinking Water Levels of Comparison (DWLOCs) because residential risks, a component of the FQPA aggregate risk assessment, exceeded the Agency's level of concern.

- Residential risks were removed from the analysis, so that only the dietary risk from food is considered for purposes of calculating the DWLOC.

- Risk estimates for ground water are based on SCI-GROW modeling, which is an unrefined assessment that provides a high-end estimate.

- Risk estimates for surface water are based on PRZM-EXAMS modeling, which is a refined, Tier II assessment that provides a high-end estimate.

- Monitoring data were not available.

- For acute risk, potential exposure to drinking water derived from either groundwater or surface water (0.9 μg/L and 979 μg/L, respectively, for all populations) result in exposure that is well below the Agency's level of concern (1499 μg/L for children 1-6 years, the most sensitive population).

- For chronic risk, potential exposure to drinking water derived from groundwater (0.9 μg/L for all populations) result in exposures that are well below the Agency's level of concern (50 μg/L for infants). However, modeling data indicate that exposure from surface water (947 μg/L for all populations; a maximum based on turf scenario) exceed the Agency's level of concern (50 μg/L for the most sensitive population).

- One degradate, bensulide oxon, was identified as a degradate of human toxicological concern. However, concentrations in the soil are expected to be low, so only the parent was considered in the assessment.

Occupational & Residential Risk

Occupational and residential handlers can be exposed to a pesticide through mixing, loading, or applying a pesticide, and reentering a treated site. Handler risk is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential handler exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

Summary of Toxicological Information

- Short-term dermal endpoint: 50.0 mg/kg/day based on a 21-day dermal toxicity study. One assessment completed for both short- and intermediate-term dermal exposures.

- Intermediate-term dermal endpoint: 50.0 mg/kg/day based on a 21-day dermal toxicity study. One assessment completed for both short- and intermediate-term dermal exposures.

- Absorption Factors: dermal absorption factor not required because 21-day dermal toxicity study was used; 100 percent used for inhalation and non-dietary oral ingestion.

- Short-term inhalation: 5.5 mg/kg/day based on a rat oral study.

- Intermediate-term inhalation: 0.5 mg/kg/day based on a 1-year oral dog feeding study.

- Non-dietary (incidental oral ingestion): 15.0 mg/kg/day based on an acute rat neurotoxicity study.

- Uncertainty Factors: 100 (10 for inter-species variability; 10 for intra-species sensitivity; and FQPA Safety Factor removed).

- MOEs were combined in order to obtain an overall risk for each applicator that accounts for both dermal and inhalation exposures. Also, where it was logical, risks associated with certain job functions were combined (e.g., a grower mixing/loading and they applying a spray solution to his own crops).

Occupational Handler Risk

- For bensulide, risk estimates were derived from *Pesticide Handlers Exposure Database*, using standard assumptions based on the exposure scenarios and types of equipment anticipated by current labeling.

- For handlers in **agricultural settings**, based on current labels (long-sleeved shirt, long pants, chemical-resistant gloves), only one scenario (high-acreage chemigation) is of concern (MOE < 100) for dermal exposure. Some high exposure scenarios are of concern for intermediate-term inhalation exposures.

- For handlers on **golf courses**, based on current labels, only two scenarios are of concern for dermal exposure: mixer/loader/applicator (M/L/A) with high pressure handwand; and M/L/A with backpack sprayer. Most scenarios are of concern for intermediate-term inhalation exposures.

- For **professional lawncare** handlers, based on current labels, four scenarios are of concern for dermal exposure: M/LA with high pressure handwand, backpack sprayer, push-type granular spreader, and bellygrinder. Most scenarios are of concern for intermediate-term inhalation exposure.

Post-Application Occupational Risk

- For workers entering a treated site, Restricted Entry Intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to re-enter. REIs are calculated in hours or days.

- **For agricultural uses**, because of bensulide's use pattern (i.e., pre-plant, pre-emergent applications on crops) the potential for post-application agricultural worker exposure is minimal.

- **For turf uses**, the occupational Restricted Entry Intervals (REIs) on turf uses were calculated using actual measured values derived from the recently submitted turf transferable residue study (TTR), which accounts for watering-in of bensulide. Watering in is required by bensulide labels for efficacy of the herbicide.

    - Following the watering in of bensulide (note that the study used about 0.5 inches of water for irrigation) MOEs are greater than 100 on the day of application even when professional handlers are completing high exposure activities at the highest application rate (MOE = 480).
    - If the watering in was not completed (i.e., using the pre-watering in data), MOEs are still greater than 100 on the day of application even when people are completing high exposure activities at the highest application rate (MOE = 150).

- The completion of separate short- and intermediate-term risk assessments for occupational bensulide post-application exposures is no longer appropriate because the selected 21-day dermal toxicity endpoint is applicable to both durations of exposure.

Residential (Homeowner) Handler Risk (from turf use only)

- When dermal exposures are combined with short-term inhalation exposures and individuals wear short pants and short-sleeved shirts (the baseline scenario for homeowner handlers), the Agency has no risk concerns (MOEs are 183 to 305) for homeowners mixing/loading/applying bensulide with a push-type granular lawn spreader.

- However, the Agency has concerns for homeowners who mix/load/apply bensulide with a bellygrinder. Combined short-term inhalation exposures at baseline result in MOEs of less than 10.

Residential (Adults & Children) Post-application Risk

Bensulide can be used in a residential setting and it can also be used on golf courses (and on other turf) where exposures to the general population can occur. As a result, both toddler and adult risks were considered in the risk assessment.

- Post-application risks for **adults** in residential settings were calculated for individuals involved in light exposure activities such as golfing and also in heavy exposure activities

such as heavy yard work.

- Following the watering in of bensulide (keep in mind the turf transferable residue study used about 0.5 inches of water for irrigation) MOEs are greater than 100 on the day of application (MOE = 150) even when people are completing high exposure activities at the highest application rates.

- If the watering was not completed (i.e., using the pre-watering in data), MOEs are still greater than 100 on the day of application (MOE = 480) even when people are completing high exposure activities at the highest application rate.

- Therefore, the Agency is not concerned about post-application exposure for residential adults.

- Post-application risks for **toddlers** in a residential setting were calculated for individuals involved in heavy exposure activities, and at the minimum and maximum application rates for bensulide. Also, risks from non-dietary ingestion (e.g., a child grabbing a handful of turf and mouthing it, or a child putting its hands in its mouth) of bensulide were calculated. (Note: non-dietary ingestion exposures were not considered in the preliminary risk assessment.)

  - Following the watering in of bensulide, the MOEs for dermal exposures were greater than 100 on the day of application even at the highest application rate for children in high exposure activities (e.g., hard play) over a long duration. If the watering in was not completed, MOEs for dermal exposures are still greater than 100 on the day of application for children in high exposure activities over a long duration, but only at the lowest application rate (MOE = 74 at highest application rate).

  - The risks associated with the mouthing behaviors of children (i.e., non-dietary ingestion) are not a concern to the Agency. Both prior to and following watering in of bensulide, MOEs are well above 100.

Aggregate Risk

Aggregate risk looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure (dermal exposure, inhalation exposure for homeowner applicators, and incidental oral exposure for toddlers who mouth grass). Aggregate exposure risk assessments are conducted for acute (1 day), short-term (1-7 days), intermediate (7 days to 3 months), and

chronic (lifetime) exposure. Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency.

- Acute aggregate exposure (food & water) to bensulide is not a concern.

- Short-term and intermediate-term aggregate exposure (food, water, residential) to bensulide are not a concern when bensulide is watered in as required by labels, and only when a spreader is used. However, if bensulide is not watered in, and/or a bellygrinder is used, aggregate MOEs are less than 100, so could pose risk concerns.

- Chronic aggregate exposure (food & water) to bensulide may be a concern based on model estimates of surface water exposures.

Ecological Risk Assessment

Nontarget Terrestrial Animal Risk

- Most significant risk is chronic avian risk (i.e., eggshell thinning) which is similar to the effects of DDT and DDE, but an approximately 10 times greater concentration of bensulide is required to produce an effect equal in magnitude. Potency approaches that of DDT, because bensulide is used at such high rates. This risk is of greater concern on turf areas, where water fowl tend to forage. Restricting bensulide use to greens and tees only would reduce the risk to birds, as water fowl would not likely forage on these areas; however, bensulide's persistence in the soil and high use rates would continue to pose chronic risk concerns.

- Acute and chronic risk to mammals through residues on wildlife food items, increased by the stability and persistence of bensulide in soil.

Nontarget Aquatic Animal Risk

- High acute risk to estuarine/marine aquatic organisms.

- Chronic risk to aquatic invertebrates. Aquatic toxicity data, submitted in April, 1999, confirmed this risk assessment.

- Run-off from turf uses is of specific concern. Risks are increased by the stability and persistence of bensulide in water and sediments.

- Risk to aquatic organisms may be lessened somewhat in southwestern areas of U.S., where the majority of bensulide-treated crops are grown, due to low rainfall.

Summary of Public Comments Comments

- Two comments specific to bensulide were received: One set was from the registrant, Gowan Company.

- Gowan commented that bensulide is only used to treat golf greens and tees; in response, the Agency added scenarios to its occupational and residential exposure risk assessment to address this.

- Gowan also commented on the Agency's dermal absorption value – this was not applied in the revised risk assessment, because Gowan submitted a 21-day dermal toxicity study that was used to determine dermal absorption.

- Gowan commented on assumptions used in the Agency's occupational and residential risk assessments, and on the appropriateness of conducting an intermediate-term exposure assessment for bensulide. With the recent submission of a turf transferable residue study and the dermal toxicity study, several of these concerns were alleviated. A comprehensive document that details the registrant's comments and the Agency's responses will be made available to the public.

- The second comment was from a weed science specialist in California, who provided information on crops grown in the southwest. This comment affected some of the risk characterizations for risk to non-target organisms.